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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,222	04/09/2004	Heidi Schmitt	334498011US	1315

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PERKINS COIE LLP/CARGILL, INC.
P.O. BOX 1247
SEATTLE, WA 98111-1247

EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/822,222	SCHMITT ET AL.	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 17 February 2006 to claims 1-3, 6, 7, 18, 20, 24, 27-29, 31 and 32 have been entered. Claims 1-36 remain pending in the current application, all claims have been considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claim 1 is directed to a method of producing a hydrolyzed lecithin product, comprising hydrolyzed phospholipids, monoglycerides, and diglycerides, the method comprising (a) contacting a lecithin material, comprising phospholipids and triglycerides, in either (i) an aqueous medium containing water and at most 5% of another water-miscible solvent or (ii) an aprotic organic solvent medium and sufficient water to promote hydrolysis, with a first enzyme which hydrolyzes the phospholipids; and (b) subsequently contacting the product of step (a) with a second enzyme, different from said first enzyme, said second enzyme being a lipase which hydrolyzes said triglycerides.

Applicant's claim 18 is directed to a method of producing a hydrolyzed lecithin product, comprising hydrolyzed phospholipids, monoglycerides, and diglycerides, the method comprising contacting a lecithin material, comprising phospholipids and triglycerides, in an aprotic organic solvent containing sufficient water to promote hydrolysis with a first and second enzymes, wherein said first enzyme is a phospholipase or lipase which hydrolyzes the phospholipids, and wherein said second enzyme, different from said first enzyme, is a lipase which hydrolyzes said triglycerides.

Applicant's claim 29 is directed to a method of producing a product comprising phospholipids, monoglycerides and diglycerides by enzymatic hydrolysis, the method comprising contacting a lecithin material, comprising phospholipids and triglycerides, in an aqueous medium or an organic solvent medium comprising an aprotic organic solvent and sufficient water to promote hydrolysis, with a lipase which selectively hydrolyzes said triglycerides.

Each of claims 1, 18 and 29 are directed to a method of producing a product, but are incomplete as they fail to recite a recovery step for the product produced. While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the **complete** process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

The term "sufficient" ("organic solvent and sufficient water to promote hydrolysis") further renders claims 1, 18 and 29 indefinite. It is critical that a small amount of water be present within the organic solvent in order to allow for proper activity of the enzyme; however, applicants fail to teach or claim the amount of water which is to be included. The term "sufficient" fails to satisfy this requirement of disclosure, as no numerical reference is provided within the claim. Therefore, because such an element is considered to be critical to the claimed method, the precise amount of water required must be clearly claimed; as is, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore the claim is rendered indefinite because one skilled in the art cannot determine the metes and bounds of the claimed subject matter.

Claims 11, 25, and 31 require the 'lecithin material' to be a retentate from a vegetable oil membrane degumming process. Degumming processes, by definition, functions to refine crude oils by separating phosphatides from triglyceride oils (See, e.g. Paulitz et al, col. 1, ln 15-17); thus the retentate

from the vegetable oil membrane degumming process would comprise phosphatides, but it would not comprise the triglycerides required by the independent claims. Therefore the retentate from a degumming process would not be suitable for applicant's claimed methods, which requires a composition comprising both phospholipids and triglycerides.

Claim 17 remains rejected as being self-dependent. The metes and bounds of the claim cannot be determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29, 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Haas et al (J American Oil Chem. Soc., 1995).

Applicant's claim 29 is directed to a method of producing a product comprising phospholipids, monoglycerides and diglycerides by enzymatic hydrolysis, the method comprising contacting a lecithin material, comprising phospholipids and triglycerides, in an aqueous medium or an organic solvent medium comprising an aprotic organic solvent and sufficient water to promote hydrolysis, with a lipase which selectively hydrolyzes said triglycerides. Claim 30 requires the solvent medium to be an organic solvent medium. Claim 32 requires the phospholipids to make up at least 50% of the lecithin mixture.

Haas et al study the hydrolytic activity of three different lipases in an organic solvent on mixtures of phospholipids and triglycerides. Haas et al used Lipase AY-30, Lipozyme IM20 and Novozyme 435 as the lipases (See Haas et al, Table 2). Haas et al used three different substrates: (i) a mixture of pure phosphatidylcholine (22 mM) and soy triglycerides (22mM) (50:50 mixture, thus phospholipids comprise

50% of lecithin); (ii) a mixture of semi-pure phosphatidylcholine (25mM) and soy triglycerides (22mM) (approximately 53:47 mixture, thus phospholipids comprise over 50% of lecithin material); and soybean soapstock (0.5g/reaction) (See Haas et al, Pg. 520, col.2). All substrates comprised a mixture of phospholipids and triglycerides, which applicant defines as a lecithin material. Each of the substrates were dissolved in hexane, 60uL of water was added to the mixtures of substrates (i) and (ii) to provide sufficient water to promote enzyme activity (See Haas et al, Pg. 520, col. 2 & Pg. 521, col. 2); then the substrate mixtures were contacted with one of the three lipases and degree of hydrolysis was measured.

Haas et al report at least the AY-30 lipase selectively hydrolyzed the triglycerides of semi-pure PC/triglyceride substrate (ii); specifically Haas et al report the AY-30 lipase completely hydrolyzed the soy triglycerides within 20 hours, but failed to hydrolyze the phospholipid component (See Haas et al, Pg. 521, col. 2- Pg. 522, col. 1). Therefore, Haas et al teach a method of producing a hydrolyzed product, said method comprising contacting a lecithin material, comprising phospholipids and triglycerides, in an aprotic organic solvent medium comprising sufficient water to promote hydrolysis, with a lipase which selectively hydrolyzes the triglycerides, in the absence of any phospholipase (Claims 29, 30 and 32). Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29, 30, 32, 33, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haas et al (J American Oil Chem. Soc., 1995).

Haas et al study the hydrolytic activity of three different lipases in an organic solvent on mixtures of phospholipids and triglycerides. Haas et al used Lipase AY-30, Lipozyme IM20 and Novozyme 435 as the lipases (See Haas et al, Table 2). Haas et al used three different substrates: (i) a mixture of pure phosphatidylcholine (22 mM) and soy triglycerides (22mM) (50:50 mixture, thus phospholipids comprise 50% of lecithin); (ii) a mixture of semi-pure phosphatidylcholine (25mM) and soy triglycerides (22mM) (approximately 53:47 mixture, thus phospholipids comprise over 50% of lecithin material); and soybean soapstock (0.5g/reaction) (See Haas et al, Pg. 520, col.2). All substrates comprised a mixture of phospholipids and triglycerides, which applicant defines as a lecithin material. Each of the substrates were dissolved in hexane, 60uL of water was added to the mixtures of substrates (i) and (ii) to provide sufficient water to promote enzyme activity (See Haas et al, Pg. 520, col. 2 & Pg. 521, col. 2); then the mixtures were contacted with one of the lipases.

Haas et al report at least the AY-30 lipase selectively hydrolyzed the triglycerides of semi-pure PC/triglyceride substrate (ii); specifically Haas et al report the AY-30 lipase completely hydrolyzed the soy triglycerides within 20 hours, but failed to hydrolyze the phospholipid component (See Haas et al, Pg. 521, col. 2- Pg. 522, col. 1). Therefore, Haas et al teach a method of producing a hydrolyzed product, said method comprising contacting a lecithin material, comprising phospholipids and triglycerides, in an aprotic organic solvent medium comprising sufficient water to promote hydrolysis, with a lipase which selectively hydrolyzes the triglycerides, in the absence of any phospholipase (Claims 29, 30 and 32).

Regarding the percentage of the substrate which was phospholipids, Haas et al teach approximately 53% of the phospholipid-triglyceride mixture was phospholipids (25 mM semi-pure phospholipids and 22 mM soy triglycerides) (See Haas et al, Pg. 520, col. 2). However, the percentage of phospholipids in the initial phospholipid-triglyceride product is a result effective variable that would be routinely optimized by one of ordinary skill in the art. It is clear that the percentage of phospholipids present in the initial substrate was a choice of experimental design, as Haas et al provided roughly equal

proportions of phospholipids and triglycerides in the initial substrate; optimization of the proportions of each component would be a routine matter based on the concentration and activity of the enzymes added to the substrate for hydrolysis. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical or produces unexpected results. Where the general conditions of a claim are disclosed by the prior art it is not inventive to discover the optimum or workable ranges by routine experimentation, See *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Also note that where the claimed ranges overlap or lie inside ranges disclosed by the prior art a prima facie case of obviousness exists. See *In re Wertheim,* 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff,* 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) (Claim 33).

Regarding the percentage acetone insoluble content and the acid value of the resulting hydrolyzed product, Haas et al does not report such measurements; however, one of ordinary skill in the art recognizes that both the acetone insoluble content and the acid value are variables that are directly controlled by optimizable parameters within the hydrolysis process. For example, the acid value is a direct result of the reaction time and the degree of hydrolysis that occurs. Additionally, the acetone insoluble content is representative of the amount of phospholipids present in the initial lecithin material; depending on the purity of the native lecithin, the percentage of phospholipids initially present in the material, and the degree of hydrolysis, the acetone insoluble content can be altered. Therefore, by increasing the phospholipid content of the starting lecithin material, by purification, or by purchasing a lecithin material with a desired high acetone insoluble content, one of ordinary skill in the art can increase the acetone insoluble content to above 60% (Claims 35 and 36). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 17 February 2006 have been fully considered. The declaration by Dr. Michael Schneider has also been fully considered.

In their response to the rejection under 35 USC 112, second paragraph, applicants state that lecithin can be interpreted to have two different meanings: in the chemistry and biochemistry art lecithin is interpreted as the molecule phosphatidylcholine; however, in the field of foods, edible oils, and food additives, the term lecithin is interpreted as a mixture of acetone insoluble polar lipids (mainly phospholipids), triglyceride oil, and other minor components produced by degumming of crude vegetable oils or animal fats. Applicants also point to paragraph 0026 of their specification for support for the intended definition of lecithin in the present application ("Lecithins... comprise a mixture of phospholipids and triglycerides, as well as lesser amounts of compounds such as glycolipids, carbohydrates, fatty acids, and/or sterols."). Based on the principle of patent law that states when more than one definition for a term is present in extrinsic references, the intrinsic record must be consulted to identify which of the different possible definitions is most consistent with applicant's use of the term (*Brookhill-Wilk & Renishaw PLC v Marposs Societa per Azioni*); thus, in the instant case, because the intrinsic record clearly does refer to lecithin as the mixture of lipids and triglycerides, the term will be given the interpretation of a mixture of phospholipids and triglycerides for the instant application. Therefore the rejection under 35 USC 112, second paragraph, relating to interpretation of 'lecithin' is withdrawn. However, new rejections under 35 USC 112, second paragraph, have been made, and the rejection over claim 17 as being self-dependent stands.

In response to the rejections under 35 USC 112, first paragraph, applicants have removed the problematic term from claim 29, thus the rejection is withdrawn.

In response to the rejections under 35 USC 102(b) over Bojsen et al, applicants argue that the lipase enzyme taught by Bojsen et al has the opposite selectivity than that currently claimed, as the lipase

of Bojsen et al selectively hydrolyzes glycolipids and phospholipids, not the triglycerides, as required by the claim. The argument is persuasive and the rejection is withdrawn. New rejections under 35 USC 102(b) have been made over Haas et al (JAOCS, 1995).

In response to the rejections under 35 USC 103(a) over Yasukawa et al, in view of various other references, applicants argue that the methods of Yasukawa et al do not involve hydrolysis of a lecithin material with a phospholipase and a lipase in the claimed solvent conditions, rather the method of Yasukawa et al involve glycerolysis and transesterification. Applicants argue that modification of the method of Yasukawa et al to arrive at the presently claimed invention would defeat the purpose of the primary reference. Applicants also argue that Sas et al is the only cited reference that does teach hydrolysis of a lecithin material, but requires an aqueous/polyol solvent, particularly glycerol in a 1:6 ratio with water. Applicants argue that the polyol, particularly glycerol is critical to the invention of Sas et al, as the method relies on transesterification of the released fatty acids (from the phospholipids) to the glycerol molecules to make mono- and diglycerides. Applicants supply a declaration by Michael Schneider to support that the use of glycerol is intended to react with the released fatty acids. The declaration cites Falcone et al and Gekko et al, but it is noted that neither of these works are relevant to the hydrolysis of lecithin.

In response, it is recognized that both the teachings of Yasukawa et al and Sas et al require transesterification, which requires the presence of glycerol in the solvent in amounts greater than what is presently allowed for in the current claims. The teachings of the art involving hydrolysis of lecithin to produce desired mono- and diglycerides and lysolecithins generally teach over hydrolysis with selective or non-selective enzymes, such as lipases and phospholipases, is undesirable as it results in formation of free fatty acids; therefore, the teachings of the art rely on esterification of fatty acids with glycerol, wherein the glycerol reacts with the free fatty acids to create more, desirable, mono- and diglycerides (See, e.g. Bornsheuer et al). Therefore, the presence of glycerol in the solvent is critical to the methods of

Yasukawa et al and Sas et al, and thus it would be repugnant to the teachings of Yasukawa et al and Sas et al to remove or reduce the glycerol used in the solvent to the claimed level, as this would result in more, undesired free fatty acids. Therefore, one would not be motivated to modify the teachings of Yasukawa et al or Sas et al to hydrolyze the lecithin material in the absence of, or in the presence of a greatly reduced amount of, glycerol, as is required by the instant invention. Thus, because modification as previously suggested would defeat the purpose of the methods of Yasukawa et al and Sas et al, the previous rejections under 35 USC 103(a) are withdrawn. However, new rejections over Haas et al have been made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651

LEON B. TARAZANO, SR.
PRIMARY EXAMINER